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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,292	03/21/2001	Borge Kringelum	030307- 0197	1783

22428 7590 07/07/2006

FOLEY AND LARDNER LLP
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EXAMINER	
DAVIS, RUTH A	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,292	KRINGELUM ET AL.	
	Examiner	Art Unit	
	Ruth A. Davis	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response filed on April 17, 2006 has been received and entered into the case. Claims 29 – 31 are added. Claims 1 – 31 are pending and have been considered on the merits. All arguments and the declaration have been fully considered.

Claim Rejections - 35 USC § 112

Rejections under 35 U.S.C. 112, second paragraph, have been withdrawn due to amendment.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1 – 7, 11, 17 – 22, 24 – 27, 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski and Christensen et al. (US 3483087).

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of

subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not

patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

4. Claims 1 – 7, 11, 17 – 22, 24 – 27and 29 - 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Christensen and Czulak.

Applicant claims a method for supplying a starter culture with a consistent quality at different propagation factories or plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c)

inoculating the mediums at different factories/plants with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality),

wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach the culture medium comprising skimmed milk. However, Czulak teaches a method of inoculating milk with a fat content of 0.3 – 1.5% (part skim and low fat milk) to produce cheese (abstract). Czulak teaches that use of skim milk enables a cheese product to be made with a substantially reduced fat content (col.1 line 10-15). At the time of the claimed invention, one of ordinary skill in the art would have been motivated by Czulak to use a culture medium including at least part skim milk in the method of Sing with a reasonable expectation of success for obtaining a dairy product with a reduced fat content.

The above references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective

variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

5. Claims 1 – 11, 17 – 22, 24 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Christensen and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different locations, (c) inoculating the mediums at different factories/plants with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the

medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium; Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The stock inoculum material or subset is liquid, frozen, or dried; the frozen inoculums are first thawed before inoculation; and the subsets are combined with an aqueous medium to obtain a suspension before cultivating. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage.

Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach the methods wherein the inoculums are liquid, frozen or dried; wherein a frozen inoculum is thawed and a dried subset is combined with an aqueous medium before inoculating into the culture medium. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to do so as a matter of routine practice. In support, Lizak teaches conventional storage of starting cultures includes liquid culture, frozen culture and dried culture (col.6 line 53-59). Although Lizak does not specifically teach frozen cultures are thawed and dried cultures are suspended in a liquid medium before inoculation, it was well known in the art to do so at the time of the invention. Therefore, at the time of the invention, one of ordinary skill in the art would have been motivated by conventional practice to obtain stock inoculum and/or subset cultures as a liquid, frozen or dried, thaw it and/or suspend the dried culture in a liquid medium because it was routine in the art as demonstrated by Lizak.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have

been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

6. Claims 1 – 7, 11 – 22, 24 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Vanderbergh and Matsummiya.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality.

The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset

inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The stock inoculum is supplied in a sealed enclosure, made from a flexible material selected from polyolefin, substituted olefin, copolymer of ethylene, polypropylene, polyethylene, polyester, polycarbonate, polyamide, acrylonitrile and a cellulose derivative; a metal foil; has a content of at least 0.01 liters; has an outlet for connecting to the culture medium container, which allows for aseptic inoculation. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a

culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to

include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach that the stock inoculum is provided in a sealed enclosure as claimed. However, Vandenbergh teaches starter cultures can be stored in leak-proof containers such as a plastic bag, plastic container, metal foil, or sealable containers (col.4 line 30-40). While Vandengergh does not teach the material used or size of such contaniers, Matsumiya discloses cell culture containers made from ethylene copolymers, polyethylene, polypropylene, acrylonitrile copolymers (col.1 line 30-37). In addition, Matsumiya teaches that the flexible, bag like structures have an inlet tube and an outlet tube with a coupler at its end (col.1 line 23-30). At the time of the claimed invention, one of ordinary skill in the art would have been motivated to provide a stock inoculum in a sealed enclosure because it was well known in the art to do so as demonstrated by Vandengergh and Maysumiya. Furthermore, it would have been well within the purview of one of ordinary skill in the art to optimize the capacity of such containers to correspond with volume of the culture as a matter of routine practice.

The references do not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

7. Claims 1 – 7, 11, 17 – 22, 24 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Kosikowski, Czulak and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The

inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products or produces desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells

and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage.

Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein each of the named organisms are used. However, at the time of the claimed invention, each of the claimed organisms were well known and used in the art as sources of starter cultures. In support, Czulak teaches a method of inoculating milk with Lactobacillus and Streptococcus cultures whereby the cultures produce a desired cheese flavor (abstract). In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Therefore, at the time of the invention, one of ordinary skill in the art would have been

motivated by routine practice to use the above named microorganisms in the method of Sing with a reasonable expectation of successfully obtaining a starter culture.

8. Claims 1 – 7, 11, 17 – 27 and 29 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sing in view of Koskowski, Rimler and Lizak.

Applicant claims a method for supplying a starter culture with a consistent quality at different factories/plants, the method comprising:

(i) providing an inoculum material comprising a concentrate of starter culture cells,

(ii) allowing the starter culture to propagate,

(iii) harvesting the cells to obtain a starter culture;

wherein step (i) comprises (a) concentrating the inoculum of step (i) to obtain a concentrated stock inoculum, (b) dividing the concentrated inoculum into subsets and providing the subsets to different factories/plants, each having a quality to inoculate a medium at different factories/plants, (c) inoculating the mediums at different locations with the subset directly into the medium; wherein the stock is subjected to a quality test and stored for 24 hours before inoculating the medium; and wherein when steps (ii) – (iii) are repeated with the another subset of the stock at different factories/plants, the starter cultures have a consistent quality. The inoculum material of step (i) is a quantity sufficient to inoculate at least 50,000 liters of culture medium, the concentrated inoculum of step (a) is at least 10^8 CFU/gram. The subset inoculum material of step (c) is directly and aseptically inoculated in the cultivation medium at a rate of 0.1%, the medium after step (c) contains at least 10^5 CFU p gram, and the medium is any conventional cultivation medium containing milk components or skimmed milk. The amount of

subset inoculum provides a ratio of CFU/g medium to CFU/g subset of 1:100 – 1:100000. The starter culture is a lactic acid selected from Bifidobacterium, Propionibacterium, Staphylococcus, Micrococcus, Bacillus, Enterobacteriacea, Actinomycetes, Corynebacterium, Brevibacterium, Pediococcus, Pseudomonas, Sphingomonas, Mycobacterium, Rhodococcus; a fungus or yeast. Specifically a lactic acid bacteria selected from Lactococcus, Lactobacillus, Leuconostoc, Pediococcus, Oenococcus and Streptococcus. The stock inoculum of (i) comprises at least 2 strains; is used in the food, feed or pharmaceutical industry; is used to inoculate milk for obtaining dairy products selected from cheese, yogurt, butter, inoculated sweet milk or liquid fermented milk products. The cells of step (ii) express desired gene products such as enzymes, active substances, polysaccharides or amino acids; or produce desired products selected from pigments, flavorings, emulsifiers, vitamins, growth stimulating compounds, food or feed additives. The quality test is selected from a disclosed group, and the stock inoculum is stored for 48 hours before adding to the culture medium; and the inoculum is shipped in a sealed enclosure.

Sing teaches a method of making a starter culture for inoculating milk to make dairy products (abstract). The method comprises inoculating an inoculum of at least 10^9 CFU/g to a culture medium, growing the cells resulting in a medium with at least 10^7 CFU/g, propagating the cells to produce a starter culture with 10^9CFU/g, harvesting the starter cells and adding the starter cells to milk to produce a dairy product (abstract). The methods are used for inoculating milk to make cultured dairy products and cheese (col.1 line 45-50). Cultures are named to include Lactococcus (examples) and other mesophiles and thermophiles known in the art (col.2 line 61-63).

Sing does not teach the method wherein the inoculum is first concentrated and divided into subsets. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to concentrate and/or divide the inoculum into subsets as a matter of routine practice and procedure. In support, Kosikowski et al. (US 5098721) teaches common practices wherein mother cultures that are transferred into multiple growth mediums (or divided into subsets), wherein the cultures are used as a bulk starter (or starter culture) (col.1). Kosikowski additionally teaches the mother culture can be concentrated for storage (col.1) prior to division and inoculation.

Sing does not teach the method wherein the inoculum is subjected to quality tests before use, or stored for 24 – 48 hours before use. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because quality tests where routinely employed in the art at the time the claimed invention was made. In addition, it was well known in the art that starter cultures can be stored before use. In support, Christensen teaches making starter cultures that are uniform with their results (or are of consistent quality), wherein the cultures are subjected to quality tests (col.6) and wherein the cultures are stable for long term storage (col.2 line 25-40). Specific tests include those standard to the industry to include acid test, activity test, test for gas, an plate count (col.6). Although the reference does not specifically say the cultures are stored for 24 or 48 hours, it does teach "long term" storage. Thus it would have been within the purview of one of ordinary skill in the art to optimize such periods as a matter of routine experimentation.

The references do not teach the method wherein the subsets are provided to different factories and/or plants. However, the location of where the actual steps take place do not

patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in different propagation factories and/or plants would materially change the method steps from those in the prior art, the claims are rendered obvious.

Sing does not teach each of the claimed "quantities sufficient", rates of inoculation, or dairy products. However, at the time of the claimed invention, it would have been well within the purview of one of ordinary skill in the art to optimize such result effective variables as a matter of routine experimentation. Moreover, at the time of the claimed invention, one of ordinary skill in the art would have been motivated by routine practice to optimize the amounts/volumes of cultures with a reasonable expectation for successfully obtaining starter cultures.

Sing does not teach the method wherein the starter cells are used in the pharmaceutical industry and express a desired gene product such as an enzyme, pharmaceutically active substance, polysaccharide or amino acid. However, at the time of the claimed invention, it would have been obvious to one of ordinary skill in the art to do so because it was a well known practice in the art at the time the invention was made. In support, Rimler teaches a method of propagating starter cells of Haemophilus in order to obtain products useful as immunological agents (abstract). Stock cultures of the bacteria are passed twice (or propagated, sub-cultured and propagated), cultured in a medium, inoculated into a starter culture tube and propagated (col.3 line 1-15) to obtain the desired pharmaceutically active substance. In further support, Lizak teaches starter cultures of fungus, Bacillus, combinations thereof and yeasts genetically altered to express enzymes (col.6 line 10-21). Moreover, at the time of the invention, one of

ordinary skill in the art would have been motivated by conventional practice to obtain a desired gene product via the methods of Sing.

Response to Arguments

Applicant argues that the references do not teach the method wherein the subsets are provided at different factories and plants. Applicant appears to argue that the step of inoculating at different factories is material to the invention, or is the cause of the consistent quality of the obtained product. Applicant argues that the inoculum is good because it is made at a one plant and is then shipped to other places. Finally applicant argues that the stock inoculum is not the same as a mother culture; that the mother cultures cannot be stored; and that the declaration of record proves a consistent qualitywhich is unexpected.

However, these arguments fail to persuade because it is maintained that the location of where the actual steps take place do not patentably distinguish the method from the prior art, since practicing the methods at different locations would not materially change the culture method. Absent evidence that practicing the method in "different locations" would materially change the method steps from those in the prior art, the claims are rendered obvious. Applicant has not provided any evidence that the resulting culture is any different than those of the prior art.

Regarding applicant's assertion that a mother culture cannot be stored, applicant is directed to the teachings of Christensen who teaches that such starter cultures can be stored for long periods of time and provide consistent quality afterwards. Thus, as stated previously,

applicant has not provided convincing evidence that one would not expect a consistent quality after performing quality tests and storing starter cultures in the production of food products.

For these reasons and those made above, the claims stand rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth A. Davis whose telephone number is 571-272-0915. The examiner can normally be reached on M-F 7:00 - 2:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 22, 2006
AU 1651

RUTH A. DAVIS
PATENT EXAMINER